REMARKS/ARGUMENTS

The rejections presented in the Office Action dated July 31, 2007 (hereinafter Office Action) have been considered. Claims 1-23 and 25-66 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claims 1, 2, 4-7, 9, 13, 15, 18, 19, 21, 22, 27, 28, 30, 48, 49, and 52 are rejected based on 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,282,444 to *Kroll et al.* (hereinafter "*Kroll*").

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (*Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. The Applicant respectfully submits that *Kroll* does not teach each and every element and limitation of independent claims 1, 18, and 48, and therefore fails to anticipate these claims.

The Applicant's independent claims 1, 18, and 48 each recite, among other features, some variation of a cardiac electrode supported by the lead body, the electrode configured for subcutaneous, non-intrathoracic placement within a patient and for one or both of cardiac monitoring and cardiac electrical stimulation.

In addressing these limitations, the Examiner cites Col. 3, Line 46 and Col. 12, Line 13 of *Kroll*, and also appears to indicate that *Kroll's* leads need only be capable of subcutaneous, non-intrathoracic placement within a patient. (Page 3).

Col. 3, Line 46 of *Kroll* fails to disclose a subcutaneous, non-intrathoracic lead configuration. Col. 12, Line 13 mentions transthoracic pacing, but provides no details regarding this configuration. In this way, *Kroll* fails to actually teach the use of a subcutaneous, non-intrathoracic lead. The contention that *Kroll's* mention of transthoracic pacing teaches the use of a subcutaneous, non-intrathoracic lead is based on mere

speculation, as one or more of the electrodes of *Kroll's* undefined transthoracic pacing system could be external of the body (i.e. non-subcutaneous).

The intracardiac lead of *Kroll* is specifically disclosed as being configured for intrathoracic implantation, and is not disclosed as being configured for subcutaneous, non-intrathoracic placement within a patient. (See Fig. 4). *Kroll* does not teach that the disclosed methods could be carried out with the intracardiac lead alternatively placed in a subcutaneous, non-intrathoracic environment. The contention that *Kroll's* leads are capable of subcutaneous, non-intrathoracic placement within a patient and still function for one or both of cardiac monitoring and cardiac electrical stimulation is mere speculation unsupported by the *Kroll* reference.

For at least this reason, the Applicant respectfully submits that the anticipation rejection of claims 1, 18, and 48 based on *Kroll* is improper.

The Applicant's independent claims 1 and 48 each recite, among other features, some variation of a pharmacological agent provided along at least a longitudinal portion of an exterior surface of the lead body. The Applicant's independent claim 18 recites a pharmacological agent provided on a portion of an exterior surface of the can.

In addressing these limitations, the Office Action notes that *Kroll* discloses a biocide that may be provided "surrounding the cardiac stimulation device." (Page 3 of Office Action; *see Kroll*, Col. 11, Lines 65-67). *Kroll* fails to teach that its biocide is or can be provided along at least a longitudinal portion of an exterior surface of its cardiac stimulation device. The Applicant respectfully submits that even if *Kroll's* biocide surrounds the cardiac stimulation device, it is not inherent that the biocide is provided along at least a longitudinal portion of an exterior surface of the lead body or on a portion of an exterior surface of the can. For example, the biocide may surround the cardiac stimulation device, but not be proximate to a longitudinal portion of an exterior surface of a lead body or on a portion of an exterior surface of the can, such that the biocide is not provided along the longitudinal exterior surface of the lead or on the can.

For at least this reason, the Applicant respectfully submits that the anticipation rejection of claims 1, 18, and 48 based on *Kroll* is improper.

The Applicant's independent claims 1 and 48 each further recite, among other features, some variation of a driving arrangement coupled to the lead, the driving arrangement configured to provide phoresis delivery of a pharmacological agent from the longitudinal portion of the exterior surface of the lead body to subcutaneous tissue. The Applicant's independent claim 18 recites a pharmacological agent provided on a portion of an exterior surface of the can, wherein the can is configured to provide phoresis delivery of the pharmacological agent from at least the portion of the exterior surface of the can to subcutaneous tissue.

In addressing these limitations, the Office Action cites Col. 11, Line 58 of *Kroll*, which the Applicant respectfully submits does not concern phoresis delivery of a biocide.

The Applicant respectfully submits that merely because *Kroll's* device delivers a pacing pulse does not mean that it is configured to provide phoresis delivery, particularly in the manner claimed.

Defining structures in terms of interrelationships or attributes they must possess has been long sanctioned in the case law. In In re Venezia, 530 F.2d 956, 189 U.S.P.Q. 149 (CCPA 1976), for example, the court made clear that language such as "each sleeve of said pair adapted to be fitted over the insulating jacket of one or said cables . . . imparts a structural limitation to the sleeve." (*Id.* at 959). The court went on to clarify that language such as "adapted to be affixed" and "adapted to be positioned" defines structures or attributes of the element in question and limits the element to those configurations which allow for the stated interrelation of the element with other structures. (*Id.*).

Moreover, assuming *arguendo*, if the Applicant's claim recitation was construed to include functional aspects, the Applicant respectfully asserts that the Office Action's disregarding of such functional aspects is inappropriate. For example, MPEP § 2173.05(g) makes clear that "A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used."

There is no teaching that any components of *Kroll's* implantable device are configured to provide phoresis delivery. Moreover, it is not inherent that *Kroll's*

implantable device just happens to be configured such that pacing pulses delivered by the device provides phoresis delivery of the biocide. For example, even though a biocide may "surround[] the cardiac stimulation device" (Col. 11, Lines 65-67), a pulse vector between electrodes may not intersect the biocide. The device may be "surrounded" by biocide, but the vector between the electrodes could still be entirely within the portion that is surrounded.

Moreover, it is not inherent that *Kroll's* implantable device just happens to be configured to provide phoresis delivery of the biocide from the longitudinal portion of the exterior surface of the lead body or from at least the portion of the exterior surface of the can to subcutaneous tissue, as claimed in independent claims 1, 18, and 48. Even if the *Kroll's* device is surrounded by biocide, it is not necessarily so that normal pacing function of the device will provide phoresis delivery of the biocide from the longitudinal portion of the exterior surface of the lead body or from at least the portion of the exterior surface of the can to subcutaneous tissue.

For each of the reasons discussed above, the Applicant respectfully submits that the rejection of independent claims 1, 18, and 48 based on *Kroll* is improper.

Dependent claims 2, 4-7, 9, 13, 15, 19, 21, 22, 27, 28, 30, 49, and 52, which are dependent from independent claims 1, 18, and 48, respectively, were also rejected under 35 U.S.C. §102(b) as being unpatentable over *Kroll*. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 18, and 48. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Therefore, dependent claims 2, 4-7, 9, 13, 15, 19, 21, 22, 27, 28, 30, 49, and 52 are also not anticipated by *Kroll*.

For at least these reasons, the Applicant respectfully submits that the rejection of claims 1, 2, 4-7, 9, 13, 15, 18, 19, 21, 22, 27, 28, 30, 48, 49, and 52 as being anticipated by *Kroll* is not sustainable, the withdrawal of which is respectfully requested.

Claims 1, 2, 4-7, 11, 16-19, 21, 22, 25, 31, 32, 48, 49, 53, and 54 are rejected based on 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,190,997 to *Darvish et al.* (hereinafter "*Darvish*").

The Applicant's independent claims 1, 18, and 48 each recite, among other features, some variation of a cardiac electrode supported by the lead body, the electrode configured for subcutaneous, non-intrathoracic placement within a patient and for one or both of cardiac monitoring and cardiac electrical stimulation.

In addressing these limitations, the Examiner cites Col. 5, Line 59 of *Darvish*, and also appears to indicate that *Darvish's* lead need only be capable of subcutaneous, non-intrathoracic placement within a patient. (Page 4).

The intracardiac lead of *Darvish* is specifically disclosed as being configured for intrathoracic implantation in or proximate the heart (Col. 13, Lines 53-58), and is not disclosed as being configured for subcutaneous, non-intrathoracic placement within a patient.

Darvish does not teach that the disclosed methods could be carried out with the intracardiac lead alternatively placed in a subcutaneous, non-intrathoracic environment. The contention that *Darvish's* lead is capable of subcutaneous, non-intrathoracic placement within a patient and still functional for one or both of cardiac monitoring and cardiac electrical stimulation is mere speculation unsupported by the *Darvish* reference.

For at least this reason, the Applicant respectfully submits that the anticipation rejection of claims 1, 18, and 48 based on *Darvish* is improper.

The Applicant's independent claims 1 and 48 each recite, among other features, some variation of a pharmacological agent provided along at least a longitudinal portion of an exterior surface of the lead body. The Applicant's independent claim 18 recites a pharmacological agent provided on a portion of an exterior surface of the can.

In addressing these limitations, the Office Action cites Col. 5, Lines 8; Col. 6, Lines 30; Col. 13, Lines 65; Col. 15, Line 12; and Col. 16, Line 23 of *Darvish.* (Page 4). The Applicant respectfully submits that the cited portions of *Darvish* fail to teach a

pharmacological agent provided along a longitudinal portion of an exterior surface of a lead body or on a portion of an exterior surface of a can.

For example, even if *Darvish* discloses that a "molecular source is integral with said at least one electrode" (Col. 5, Line 8) and later that "one electrode comprises a linear electrode" (Col. 6, Line 30), it is not necessarily the case that the molecular source is then provided along at least a longitudinal portion of an exterior surface of the lead body. The molecular source could be disposed on a single point on, or even a ring around, the electrode. As such, the area of deposition is not necessarily along a longitudinal portion of the linear electrode.

Moreover, *Darvish* fails to teach that the molecule is disposed on the casing of the device (Col. 13, Line 65).

Also, Col. 15, Line 12 discusses general provision of a molecule, and not specific placement on a lead or can.

Although *Darvish* discloses a catheter (Col. 16, Line 23), the catheter merely delivers the molecule within the "vicinity of electrode 192" (Col. 16, Line 22; See Fig. 5).

As such, the Applicant respectfully submits that the cited portions of *Darvish* fail to provide a teaching of a pharmacological agent provided along at least a longitudinal portion of an exterior surface of the lead body, as cited independent claims 1 and 48, or a pharmacological agent provided on a portion of an exterior surface of the can, as recited in independent claim 18.

For at least this reason, the Applicant respectfully submits that the anticipation rejection of claims 1, 18, and 48 based on *Darvish* is improper.

The Applicant's independent claims 1 and 48 each further recite, among other features, some variation of a driving arrangement coupled to the lead, the driving arrangement configured to provide phoresis delivery of a pharmacological agent from the longitudinal portion of the exterior surface of the lead body to subcutaneous tissue. The Applicant's independent claim 18 recites a pharmacological agent provided on a portion of an exterior surface of the can, wherein the can is configured to provide phoresis delivery of

the pharmacological agent from at least the portion of the exterior surface of the can to subcutaneous tissue.

Although *Darvish* discloses iontophoresis (Col. 1, Lines 33-37), the cited portions of *Darvish* fails to teach that the implantable system is configured to provide phoresis delivery of a pharmacological agent from the longitudinal portion of the exterior surface of the lead body or from at least the portion of the exterior surface of the can to subcutaneous tissue, as claimed in independent claims 1, 18, and 48. For example, *Darvish* is primarily concerned with delivering a molecule from the distal end of a lead directly into cardiac tissue (*see* Col. 15, Lines 30-55; Fig. 4), not from the longitudinal portion of the exterior surface of a lead body to subcutaneous tissue or from at least the portion of the exterior surface of a can to subcutaneous tissue.

For each of the reasons discussed above, and reasons discussed above with regard to similar prior art configurations, the Applicant respectfully submits that the rejection of independent claims 1, 18, and 48 based on *Darvish* is improper.

Dependent claims 2, 4-7, 11, 16, 17, 19, 21, 22, 25, 31, 32, 49, 53, and 54, which are dependent from independent claims 1, 18, and 48, respectively, were also rejected under 35 U.S.C. §102(b) as being unpatentable over *Darvish.* While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 18, and 48. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Therefore, dependent claims 2, 4-7, 11, 16, 17, 19, 21, 22, 25, 31, 32, 49, 53, and 54 are also not anticipated by *Darvish.*

For at least these reasons, the Applicant respectfully submits that the rejection of claims 1, 2, 4-7, 11, 16-19, 21, 22, 25, 31, 32, 48, 49, 53, and 54 as being anticipated by *Darvish* is not sustainable, the withdrawal of which is respectfully requested.

Claims 55, 58, and 64 are rejected based on 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over *Kroll.*

The Applicant's independent claim 55 recites a lead coupled to the can, the lead comprising a lead body, a cardiac electrode coupled to the lead body, and one or more conductors coupled to the cardiac electrode and disposed within the lead body, the electrode configured for subcutaneous non-intrathoracic placement within a patient and for one or both of cardiac monitoring and cardiac electrical stimulation; a first pharmacological agent provided along at least a longitudinal portion of an exterior surface of the lead body; and a second pharmacological agent provided on a portion of an exterior surface of the can; and a driver apparatus detachably coupled to the implantable medical device, the driver apparatus configured to facilitate phoresis delivery of at least one of the first pharmacological agent from the longitudinal portion of the exterior surface of the lead body and the second pharmacological agent from the portion of the exterior surface of the can.

For each of the reasons discussed above in connection with the §102(b) rejection based on *Kroll*, the Applicant respectfully submits that the rejections based on *Kroll* do not account for the following claim limitations:

- a lead body, a cardiac electrode coupled to the lead body, and one or more conductors coupled to the cardiac electrode and disposed within the lead body, the electrode configured for subcutaneous non-intrathoracic placement within a patient and for one or both of cardiac monitoring and cardiac electrical stimulation

- a first pharmacological agent provided along at least a longitudinal portion of an exterior surface of the lead body

- a second pharmacological agent provided on a portion of an exterior surface of the can

- a driver apparatus detachably coupled to the implantable medical device, the driver apparatus configured to facilitate phoresis delivery of at least one of the first pharmacological agent from the longitudinal portion of the exterior surface of the

lead body and the second pharmacological agent from the portion of the exterior surface of the can

As such, the Applicant respectfully submits that the §102(b) and §103(a) rejections of independent claim 55 are improper.

Each of claims 58 and 64 depend from independent claim 55. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claim 55. These dependent claims includes all of the limitations of the base claim, and recite additional features which further distinguish these claims from the cited references. Moreover, if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. (*In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Therefore, dependent claims 58 and 64 are not anticipated, nor rendered *prima facie* obvious, by *Kroll*.

As such, the Applicant respectfully requests withdrawal of the §102(b) and §103(a) rejections of claims 55, 58, and 64 and notification that these claims are in condition for allowance.

Claims 55, 56, 65, and 66 are rejected based on 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over *Darvish*.

For each of the reasons discussed above in connection with the §102(b) rejection based on *Darvish*, the Applicant respectfully submits that the rejections based on *Darvish* do not account for the following claim limitations:

- a lead body, a cardiac electrode coupled to the lead body, and one or more conductors coupled to the cardiac electrode and disposed within the lead body, the electrode configured for subcutaneous non-intrathoracic placement within a patient and for one or both of cardiac monitoring and cardiac electrical stimulation

- a first pharmacological agent provided along at least a longitudinal portion of an exterior surface of the lead body

- a second pharmacological agent provided on a portion of an exterior surface of the can

- a driver apparatus detachably coupled to the implantable medical device, the driver apparatus configured to facilitate phoresis delivery of at least one of the first pharmacological agent from the longitudinal portion of the exterior surface of the lead body and the second pharmacological agent from the portion of the exterior surface of the can

As such, the Applicant respectfully submits that the §102(b) and §103(a) rejections of independent claim 55 are improper.

Each of claims 56, 65, and 66 depend from independent claim 55. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claim 55. These dependent claims includes all of the limitations of the base claim, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 56, 65, and 66 are not anticipated, nor rendered *prima facie* obvious, by *Darvish.*

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 55, 56, 65, and 66 and notification that these claims are in condition for allowance.

Claims 3, 8, 10, 12, 14, 20, 23, 26, 29, 50, 51, 53, 57, and 63 are rejected based on 35 U.S.C. §103(a) as being unpatentable over *Kroll,* or in the alternative, *Darvish.*

Each of claims 3, 8, 10, 12, 14, 20, 23, 26, 29, 50, 51, 53, 57, and 63 depend from one of independent claims 1, 18, 48, and 55, respectively. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims

claims 1, 18, 48, and 55. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 3, 8, 10, 12, 14, 20, 23, 26, 29, 50, 51, 53, 57, and 63 are not made obvious by *Kroll*, or in the alternative, *Darvish.*

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 3, 8, 10, 12, 14, 20, 23, 26, 29, 50, 51, 53, 57, and 63 and notification that these claims are in condition for allowance.

Claims 59-62 are rejected based on 35 U.S.C. §103(a) as being unpatentable over *Kroll,* or in the alternative, *Darvish.*

Each of claims 59-62 depend from independent claim 55. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claim 55. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 59-62 are not made obvious by *Kroll*, or in the alternative, *Darvish.*

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 59-62 and notification that these claims are in condition for allowance.

It is to be understood that the Applicant does not acquiesce to the Examiner's characterization of the asserted art or the Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to the Applicant's claimed subject matter. Moreover, the Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art, what things are capable of, what is well known in the art, common knowledge at the time of the Applicant's invention, officially noticed facts, and the like. The Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching and suggestion of various features recited in the Applicant's pending

claims. The Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in the future.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.626PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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